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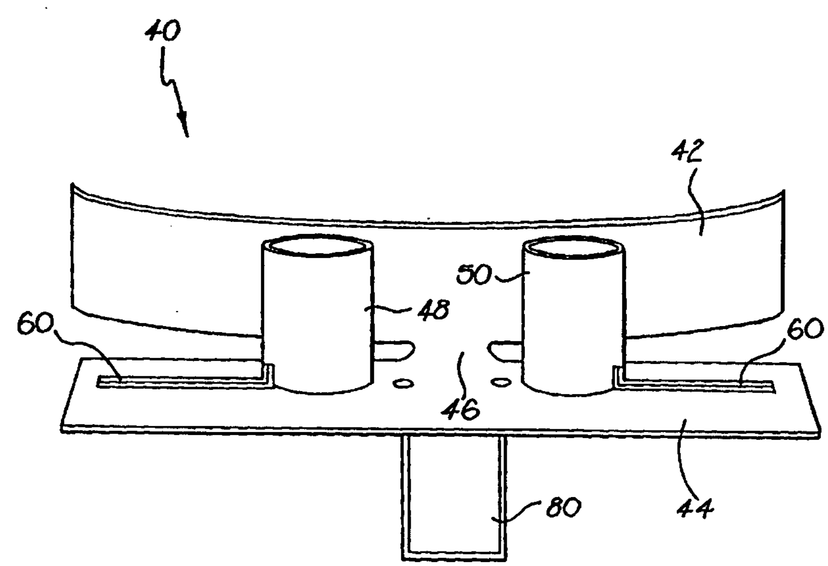

(57) Abstract

Apparatus (40) for monitoring oro-nasal respiratory flow is disclosed. The apparatus (40) is formed of a curved plate (42) to which is substantially perpendicularly arranged a planar member (44), the plate (42) and the member (44) are connected by a neck portion (46). Mounted in an upstanding fashion from the planar member (44) are two nasal prongs (48, 50). Two PVDF sensors (60) are mounted from, and lie in, the plane of the planar member (44), co-operating with a respective nasal prong (48, 50). A further PVDF sensor (80) in planar form is arranged to be downwardly directed and perpendicular to the planar member (44) so as to be located in the vicinity of the mouth when the apparatus (40) is being worn by a patient. The PVDF sensors (60, 80) deflect respectively under the influence of nasal and oral airflow, and generate electrical charge having a determined relationship with the airflow.

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APPARATUS AND METHODS FOR ORO-NASAL RESPIRATION MONITORING

Field of the Invention

This invention relates to apparatus and methods for monitoring oral and/or nasal respiration.

Background of the Invention

In the medical study of respiration, including monitoring during sleep, it often is important to detect and classify respiration using the least invasive method possible. To this end the measurement of airflow in the proximity of the nose and mouth (i.e. oro-nasally) is an established technique. Although the majority of people breath through their nose while asleep it is important also to monitor oral airflow. The failure also to monitor oral airflow can lead to misinterpretation of mouth breathing as a cessation (apnea) or reduction (hypopnea) in respiration.

One of two methods of measurement are conventionally used to monitor oro-nasal airflow. The first is based on the location of a thermistor (or thermistors) in the oral and nasal airflows, as shown in Fig. 1. The thermistors 1 are connected to electronic circuitry 2 which measures their electrical resistance and outputs a signal 3 indicative of this resistance and changes therein. Airflow past the thermistor is measured by the increase in temperature of the exhaled air relative to ambient, as shown in Fig. 2, or alternatively by the cooling effect of a moving airflow past a thermistor which is warmed above ambient by an electrical current passing through it.

While this method of measurement is convenient and cheap, the low frequency cut-off point of the filtering circuitry necessary to remove noise from the flow signal to make it useable also removes higher frequency elements indicative of snoring or respiratory flow limitation. The phase response of such filtering also may distort the timing of respiration.

A second known method of measuring oro-nasal airflow, shown in Fig. 3, uses the well known pitot tube or Bernoulli effect, whereby a pressure which varies with flow rate is generated in a tube 4 by placing its open end parallel with, or at some intermediate angle to, the flow. The other end of the tube terminates at an electrical pressure transducer 5, the output signal 6 of which thus varies with flow rate.

Unlike the thermistor technique, the flow measurements derived from the pressure transducers 5 have a bandwidth adequate for detecting both snoring and flow limitation. Fig. 4 shows a typical pressure signal illustrating both instances. Such systems are routinely used for the detection of nasal respiration, but their use in measuring oral respiration is problematic due to the lower flow velocities often found in the wider oral cross-section compared to the narrower nasal passageway.

When the pressure transducer prior art method is used to measure both nasal and oral airflow, normally only one pressure transducer is fed by two sources. Two tubes 7 are located at the periphery of or just inside the nares, and another single (or double) tube 8 is located in the vicinity of the lips, as shown in Fig. 5. These tubes join downstream into a common tube 9 in communication with the circuitry 5.

Oral flow measured in this way gives a significantly lower output (typically a factor of 6) from the pressure transducer than nasal flow. Additionally, the oro-nasal tube configuration further attenuates the oral flow by a factor of about two because for zero nasal flow there is a pressure drop down the tubing path from the oral inlet 8 to the nasal inlets 7, as exemplified in Fig. 6. This pneumatic "potential divider" effect is present in all configurations where two tube inlets join together via similar tubes.

The sensitivity of the oral channel also is highly dependent on the positioning of the oral tube 8. As shown in Figs. 7a and 7b, if the tube end 10 is located in the centre of the airflow for exhalation with slightly opened lips 11 it will become insensitive if the mouth is opened further and the airflow profile changes.

This arrangement is somewhat cumbersome by requiring lengths of tubing passing from the patient to the pressure transducer. The tubing can become fouled and thus displaced from the required monitoring site.

Reference also can be made to U.S. Patent No. 5,311,875 in the name Peter Strasz, issued 17 May 1994.

The present invention is directed to overcoming or at least ameliorating one or more of the problems associated with the prior art techniques in monitoring respiratory flow from the nose and/or mouth.

Summary of the Invention

In one broad form the invention discloses apparatus for monitoring respiratory airflow, the apparatus comprising means for conveying respiratory airflow past flow sensor means, said flow sensor including: a cantilevered member to deflect under the influence of said airflow and piezo-electric material that responds to said deflection to generate charge that is indicative of respiratory airflow.

In another embodiment the apparatus can be for monitoring oral respiratory flow, the flow sensor means, when in use, is located in front of a patient's mouth.

The cantilevered member can be formed as a laminate comprising a strip of said piezo-electric material arranged between two planar metallic electrodes, each electrode in turn being covered by a sheet of plastics material, and wherein the sheets of plastics materials can be of a different thickness to each other.

The piezo-electric material can be polyvinylidene fluoride (PVDF). The material also can exhibit pyro-electric properties, as is the case for PVDF in which case said charge can include a component due to a temperature gradient occurring by virtue of respiratory airflow.

In one preferred embodiment the apparatus can be for monitoring nasal respiration, in which said airflow conveying means comprises nasal tube means conveying nasal airflow past said flow sensor means.

In a particularly preferred form, the nasal tube means comprises two nasal tubes and two respective nasal flow sensors arranged so that at least a portion of each nasal flow sensor is located inside a respective nasal tube. In one form, a nasal flow sensor comprises a cantilevered beam at the free end of which is provided a paddle. The paddle can be substantially the same shape as the lateral cross-section of the respective nasal tube. The piezo-electric material can extend over part or all of the beam. If the piezo-electric material extends to the paddle, or is thermally coupled to it, and also is pyro-electric, it can also respond to the changing temperature of respiratory inspiration and expiration to generate a charge that is indicative of nasal respiration.

The apparatus can further comprise a body from which one or two nasal airflow sensors and an oral flow sensor are mounted. The body can comprise a curved plate adapted to fit in the region between the nose and the upper lip of a patient, and a planar member arranged substantially perpendicularly to the curved plate. The nasal flow sensor(s) and the mouth sensor preferably are mounted from the planar member. The apparatus can further comprise means to releasably secure the body to the patient's head, including elasticised straps that can pass behind the patient's head or loop around the ears.

The metallic electrodes can be connected to at least a pair of terminals from which an electrical signal indicative of nasal and/or oral respiratory airflow can be obtained. The terminals can be coupled to signal processing means to discriminate at least the occurrence of flow and snore from said signal.

In another form, the invention discloses continuous positive airway pressure (CPAP) treatment apparatus providing difference CPAP treatment pressures during inspiration and respiration respectively, the apparatus comprising:

a controllable flow generator for the supply of breathable gas at pressures elevated above atmospheric pressure;

a delivery tube coupled to the flow generator;

a patient mask coupled to the delivery tube to receive said supply of breathable gas;

cantilevered flow sensor means being that can deflect under the influence of patient respiratory airflow and that includes piezo-electric material that responds to said deflection to generate an electrical signal indicative of respiratory airflow; and

control means operable to control said flow generator and, in turn, the pressure of said supplied breathable gas, and to receive said electrical signal and sense transitions between inspiration and respiration therefrom for said different CPAP treatment pressures.

In yet another broad form, the invention discloses a pressure transducer, the transducer comprising a cantilevered beam that includes over at least a portion of its length a piezo-electric material that develops charge in response to deflection of the beam in turn in response to gas flow. The charge is scalable at least by the surface area of the transducer exposed to the flow to directly measure pressure. The transducer can include a paddle at its distal end. Preferably, the paddle is placed in a gas path. The gas path can be a conduit, a nose or mouth mask, nasal prongs or the like.

In another broad form the invention further discloses a method for monitoring nasal and/or oral respiration, the method comprising the steps of:

subjecting piezo-electric material to respectively nasal and/or oral airflow to result in a mechanical strain applied to said material thereby inducing an electrical charge; and

collecting said charge by electrodes coupled to said piezo-electric material to form an electrical signal indicative of nasal and/or oral respiration.

The method can further comprise the step of calibrating said electrical signal to quantitatively measure nasal respiratory airflow. The nasal respiratory flow signal can be signal-processed to give a measure of any one or more of: respiratory rate, minute volume, the occurrence of an apnea or hypopnea and flow limitation.

The method can further comprise the step of subjecting the piezo-electric material, that also exhibits pyro-electric effects, directly to nasal airflow to result in a temperature change inducing an electrical charge, further indicative of nasal respiration.

The method yet further comprises the step of subjecting a pyro-electric material to a source of oral airflow to result in a temperature change inducing electrical charge indicative of oral respiration.

In all the foregoing methods the piezo-electric and/or pyro-electric material can be PVDF material.

The method can further comprise the step of coupling the collected charge to signal processing means to monitor at least oro-nasal respiratory flow and snore.

Brief Description of the Drawings

Embodiments of the invention now will be described with reference to the accompanying drawings, in which:

Figs. 1 to 7 are prior art arrangements as already discussed;

Fig. 8 is a cross-sectional view of a laminate structure utilised in the construction of an embodiment;

Fig. 9 is a perspective view of apparatus for the monitoring of oro-nasal flow;

Fig. 10 is an underside plan view of the apparatus of Fig. 9;

Fig. 11 is a view of the apparatus of Fig. 9 when worn by a patient;

Fig. 12 shows detail of the co-operating arrangement of component parts of the apparatus of Fig. 9;

Fig. 13 shows the x-y-z directions of mechanical stress/strain on a PVDF sensor;

Fig. 14 is a plan view of a blank for component parts of the apparatus of Fig. 9;

Fig. 15 is a connection diagram pertaining to the apparatus of Fig. 9;

Fig. 16 is a schematic block diagram of instrumentation and signal processing of oro-nasal flow measured by the apparatus of Fig. 9 when in use; and

Fig. 17 shows a calibration curve for the cantilever sensor.

Description of Preferred Embodiments and Best Mode

The embodiments to be described make particular reference to the monitoring of at least nasal respiratory airflow, and preferably oro-nasal flow, for the diagnosis of obstructive sleep apnea (OSA) and other associated conditions, including the occurrence of partial upper airway occlusion. It is to be understood, however, that the apparatus and methods to be described have application where the monitoring of oro-nasal flow and other related parameters, such as respiration rate, minute volume, snoring and flow limitation are important. The measurement can be for the purposes of both diagnosis and treatment. Treatments can take the form of continuous positive airway pressure (CPAP) or assisted respiration. Furthermore, CPAP treatment can be triggered by the determination of respiratory flow.

The embodiments described make use of the material polyvinylidene fluoride (PVDF), which is a material exhibiting both piezo- and pyro-electrical characteristics. Any other piezo- and pyro-electric material can equally be used. For cantilevered-type sensors alone, it is sufficient for the material to exhibit only piezo-electric properties. That is, charge is generated by the PVDF material in response to pressure (strain) and temperature, and so an electrical sensor/transducer can be derived. PVDF is manufactured in flexible films, and one supplier is the U.S. company AMP, through its subsidiary Flexible Film Sensors, of P.O. Box 799, Valley Forge, PA 19482.

In order to utilise the PVDF material in the form of a sensor to detect both strain and temperature, the material in the form of a sheet 22 is encapsulated in a laminate structure of the form shown in Fig. 8. In this figure, a laminate 20 is formed as a sandwich-type construction. The PVDF sheet 22 lies between two planar electrodes 24,26 typically formed from silver or other like metallic conductor. The

electrodes 24,26 in turn are covered by a transfer adhesive 28. This adhesive finally is covered by sheets of plastics material 30,32 to complete the laminate 20. The top sheet 30 is thicker than the bottom sheet 32. The disparate thickness of the plastics sheets 30,32 ensures that the neutral axis of the laminate 20 is outside the PVDF sheet 22, which significantly increases the charge developed between the electrodes 24,26 when the PVDF sheet 22 is subjected to mechanical strain. The PVDF laminate 20 is commercially available from the above-noted source in the completed form as just described.

Figs. 9 to 12 show an apparatus 40 for monitoring oro-nasal flow that utilises the PVDF laminate 20. The apparatus is formed of a curved plate 42 to which is substantially perpendicularly arranged a planar member 44, the plate and the member are connected by a neck portion 46. Mounted in an upstanding fashion from the planar member 44 are two nasal prongs 48,50. Two PVDF sensors 60 are mounted from, and lie in, the plane of the planar member 44, co-operating with a respective nasal prong 48,50 as presently will be described. A further PVDF sensor 80 in planar form is arranged to be downwardly directed and perpendicular to the planar member 44 so as to be located in the vicinity of the mouth when the apparatus 40 is being worn.

Fig. 11 shows the apparatus being worn by a patient such that it is supported from the patient's head by means of elasticised straps 52 passing in loops around the ears or the back of the head, with the curved plate 42 being located in the region between the nares and the upper lip. Any other form of releasable securing means can be utilised, including head bands or straps. The nasal prongs 48,50 are inserted into the nares, resulting in the PVDF sensor 80 being located directly in front of the mouth. The mouth sensor 80 located is sized so as to be in the path of air or breathable gas inspired or expired by the mouth at any degree of opening.

The underside plan view of Fig. 10 shows the arrangement of the nasal prong 48,50 and the PVDF sensors 60 in greater detail. For convenience, two different types of sensors 60 have been shown, the first being a full cantilevered-type 62 and the

second being a partial cantilevered-type 64. Whilst two types have been shown, it usually would be the case that two of the same type of PVDF sensor is utilised in any particular oro-nasal monitoring apparatus 40. The cantilevered sensors 62,64 are arranged to be within a space 66 formed in the planar member 44 and as circumscribed by the lower extent of the nasal prongs 48,50. Both of the cantilevered sensors 62,64 comprise a beam 70 fixed at one end to the planar member 44 and a free end thereof a paddle 72. The paddles are disc-shaped in consequence of the circular cross-sectional shape of the nasal prongs. However, the paddles can equally be of any other convenient shape without necessarily being the same as the surrounding nasal prongs.

The full cantilevered sensor 62 and partial cantilevered sensor 64 differ in as much as the layer of PVDF material 22 forming a part of the laminate 20 from which the sensors are constructed extends only along a portion of the beam 70 and does not form a part of the disk 72 located within the passageway 74 formed by the nasal prong 50.

In distinction, the full cantilevered sensor 62 is formed entirely from the laminate 20 as described in Fig. 8, with the mechanical properties of the plastics sheets 30,32 being chosen in order to achieve the desired electrical response on deflection in consequence of nasal respiratory flow and the desired dynamic (high frequency) mechanical response.

Fig. 12 is an exploded-view of only one of the nasal prongs 48 and the respective full cantilevered sensor 62. Movement of nasal respiration through the passageway 74 defined by the nasal prong 48 is converted into a deflective motion of the cantilever sensor 62 by virtue of the airflow impinging on the paddle 72. The nasal prong 48 includes a cut-out portion 76 that allows for unrestricted movement of the beam 70. The cut-out portion 76 can also be enclosed or sealed to prevent air spilling out.

Representative dimensions for the cantilevered sensors 62,64 are as follows:

- Width of the beam (70) = 2 mm.

- Length of the beam (70) = 15 mm.
- In a diameter of the passageway (74) = 7.5 mm.
- Diameter of the disc (72) = 6.5 mm.
- Thickness of the beam (70) = 200 μm.
- Thickness of PVDF sheet (22) = 28 μm.
- Thickness of electrode layers (24,26) = 6 μm.
- Thickness of top plastics sheet (30) = 125 μm.
- Thickness of bottom plastics sheet (32) = 25 μm.

Experimentation conducted by the inventors has determined the following relations in relation to a cantilevered sensor constructed in accordance with the foregoing dimensions. Firstly, for a given deflection force the width of the beam 70 has no influence on the charge generated by the PVDF sheet 22. The minimum thickness of the beam 70 produces the maximum charge output. In a similar way, the maximum length of the beam 70 will produce the maximum charge output, however that length has an influence on the mechanical resonance of the cantilevered beam - the longer the length, the lower the resonant frequency. The cross-sectional area of the beam 70 will seek to maximise stress, hence strain in the PVDF sheet, but also has to consider the electrode surface area. Broadly speaking, the maximum electrode surface area will result in maximal charge, subject to the considerations already mentioned.

Other considerations apply in relation to the cantilevered sensor 62,64 so far as the composite materials are concerned. The neutral axis of the beam 70 preferably lies on the surface of the PVDF sheet 22. The top plastics sheet 32 can have any Young's modulus, however that value has to match with the neutral axis, and is related to the resonant frequency. The bottom plastics sheet 32 must have a minimal Young's modulus, and is related in thickness and Young's modulus to the neutral axis.

The charge developed for a cantilevered-type sensor of the type generally shown in Fig. 12 can be expressed as follows:

$$Q = p \cdot \Delta T \cdot A$$

where T = Temperature, A = exposed surface area (convection and radiation),

p = pyroelectric coefficient = $30 \cdot 10^{-6}$ C / (K $\cdot$ m^2)

The charge developed due to mechanical stress/strain can be expressed as:

$D = Q / A = d_{3n} \cdot \sigma_n$

where n is an indicator of direction, as shown in Fig. 13, and further wherein:

D = charge density developed,

Q = charge developed,

A = conductive electrode area,

d_{3n} = appropriate piezoelectric coefficient for the axis of applied stress or strain, and

σ_n = stress applied in the relevant direction (in the PVDF material)

The cantilevered-type sensor shown in Fig. 12 can also be utilised as a pressure transducer. Once respiratory flow has been measured and calibrated (as described presently), it is a simple matter of scaling flow by a multiplying factor corresponding to the surface-area of the sensor exposed to the flow to arrive at a quantitative measure of pressure.

The full cantilevered sensor 62 responds both to the mechanical strain developed by virtue of nasal respiratory flow and to heating effects for reason of being under the direct influence of expired air that is at body temperature and inhaled air at room temperature, thus creating a temperature gradient. The typical temperature performance of PVDF material is 30 x 10^{-6} coulombs/K$\cdot$$m^2$. On the other hand, the partial cantilevered member 64 detects nasal respiratory flow primarily by virtue of a strain effect, since the PVDF material is only located along the beam 70 and not on the paddle 72, and so is out of the influence of nasal flow.

An advantage of the cantilevered-type sensors 62,64 is their frequency response. For sensors of the characteristic dimensions described, the bandwidth is in the range <0.001-80 Hz, with the signals at frequencies in excess of 20 Hz being

measurable exclusively by virtue of the cantilevered (piezo-) arrangement. That is, the pyro-electrical effect of the PVDF material 22 is frequency limited to approximately 5 Hz. By virtue of the cantilevered-type sensors 62,64 it is possible to detect and measure snoring, that being characterised by nasal flow in the frequency range 30-150 Hz.

The PVDF sensor 80 is mounted to be somewhat also cantilevered, however, the surface area of the PVDF laminate 20 forming the sensor 80 is small when compared with the cross-sectional area of the mouth when opened, and so the mechanical strain effect on the sensor is small. Thus the primary effect of mouth respiration is by the effect of temperature, again for reason of exhaled air being at body temperature and inhaled air being at room temperature, constituting a temperature gradient.

The mouth sensor 80 can also be of larger surface area than as has been shown in Figs. 9 and 11. In the alternative, two additional sensors can be mounted from the planar member 44 to be arranged at the corners of the mouth.

The mouth PVDF sensor 80 ensures that for a patient who is mouth-breathing only, it will not mistakenly be determined that the patient is experiencing an apnea, as might otherwise be done if there only was nasal respiration monitoring.

Fig. 13 shows a blank from which both the mouth PVDF sensor 80 and the two cantilevered sensors 60 can be formed. In this way, sensors can be cheaply mass-produced by means of stamping, or laser/die cutting, then integrated into an injection molded structure forming the curved plate 42, the planar member 44, the neck portion 46 and the nasal prongs 48,50. The blank shown in Fig. 13 is at an exaggerated scale, and its actual size can be determined from the scaled-up 1 mm increments shown on that drawing.

Fig. 15 shows an electrical circuit diagram from which it can be seen that the three sensors (the two nasal cantilever-type sensors 60 and the mouth sensor 80) are inter-connected so that the signals they generate sum, by virtue of the sensors being in a

parallel arrangement. By utilising the circuit arrangement 90 shown in Fig. 13, it is only necessary to form a single pair of terminals connecting with the electrode layers 24,26, since the arrangement of the PVDF laminate 20 results in the summing of all charge developed through the various piezo- and pyro-electrical effects.

In a different form, the nasal sensors 60 may be electrically separated from the mouth sensor 80 to achieve separate oral and nasal outputs for signal processing. This can be achieved by arranging for the PVDF laminate sheet 20, such as shown in Fig. 13, to have a discontinuity in the PVDF material 22 in the region shown by the dashed lines. A reason for doing so would be to discriminate between nose and mouth breathing, so that in the instance of no nasal flow being detected a check can be made for mouth respiratory flow before determining whether an apnea may be occurring.

The schematic block diagram of Fig. 15 shows the circuit 90 connected with a charge amplifier 100 to convert the sensor charge into an analog electrical signal that is passed to a 50 (or 60) Hz notch filter 102 that removes any contribution due to mains frequency power supplies. The resulting signal then is passed to a signal processing analyser and associated display 104.

Once the output from the terminals 92,94 is calibrated against flow, it is then a conventional signal processing procedure to determine the parameters such as respiration rate, minute volume, the occurrence of apnea or hypopnea, snoring (by Fourier frequency transform or band-pass filtering), flow limitation and flow itself. For a cantilever-type sensor of the type described above, calibration can be determined experimentally if the flow also is measured. Fig. 17 shows a plot of data points for flow vs. output of the charge amplifier 100, from which a calibration quadratic curve fit equation was developed. It may be desired to electronically linearise the sensor output, however that is simply an electronic scaling and somewhat superfluous once the calibration is achieved.

So far as the mouth sensor 80 is concerned, the pyro-electric effect of the PVDF material is utilised to qualitatively determine whether there is mouth breathing.

It may be desired only to utilise a single nasal tube and measure nasal flow from one nasal passageway only. This may be desired when the occurrence of nasal flow and snore are required to be detected but not measured with precision.

As an extension, if it is of no particular concern to determine that mouth breathing is occurring, then it may be desired not to provide a mouth sensor.

The cantilevered sensors can be of a different non-regular profile/configuration to those shown in Figs. 10 and 12 to account for sensitivity and scaling considerations. One such arrangement can behave so as to produce an electrical output that is directly proportional to flow, thus obviating the step of electronic linearisation.

In relation to CPAP apparatus, a cantilevered-type sensor 62,64 of the type previously described can be utilised in conjunction with the provision of CPAP treatment. One or two sensors can be located generally in the region of the nares inside a nose (or nose and mouth) mask so that they are exposed to respiratory nasal air flow and yet do not impede the positive pressure of air applied at the entrance to the patient's airway. A cantilevered-type sensor also could be located in the vent hole of the mask or in the conduit supplying the air or breathable gas to the mask, whether that be near the junction of the conduit with the mask or near or within the flow generator. A sensor located in any of these ways will still provide a measure of respiratory flow, and particularly will accurately identify respiratory transitions between inspiration and expiration (and vice versa). In this way, the output signal generated by the sensor can be provided to the control circuits of the CPAP apparatus as an accurate determination of such transitions. Such a control signal thus can act as a trigger for bi-level CPAP treatment or in the estimation of breath-by-breath volume. In the former case in this way, the CPAP apparatus can be controlled in accordance with detection of a transition between inspiration and expiration to control the adjustment of CPAP treatment pressure relative to the higher inspiratory treatment pressure and the expiratory treatment pressure. A sensor of the type described therefore can be simply integrated

into the commercially-available bi-level CPAP apparatus manufactured by the present applicant.

CLAIMS:

1. Apparatus for monitoring respiratory airflow, the apparatus comprising means for conveying respiratory airflow past flow sensor means, said flow sensor including: a cantilevered member to deflect under the influence of said airflow and piezo-electric material that responds to said deflection to generate charge that is indicative of respiratory airflow.

2. Apparatus as claimed in claim 1, the apparatus being for the monitoring of nasal respiratory flow, and wherein said airflow conveying means comprises one or more nasal tubes conveying nasal airflow to said flow sensor means.

3. Apparatus for monitoring oral respiratory airflow, the apparatus comprising a frame, from which a cantilevered member is arranged to deflect under the influence of said airflow, the member including piezo-electric material that responds to said deflection to generate charge that is indicative of oral respiratory airflow.

4. Apparatus as claimed in any one of claims 1 to 3, wherein the member is a laminate structure comprising a strip of piezo-electric material arranged between two planar metallic electrodes, each electrode being covered by a sheet of plastics material.

5. Apparatus as claimed in claim 4, wherein said sheets of plastics materials are of a different thickness to each other.

6. Apparatus as claimed in claim 4 or claim 5, wherein the piezo-electric material is polyvinylidene fluoride (PVDF).

7. Apparatus for monitoring respiratory airflow, the apparatus comprising:

two nasal tubes respectively to be received in a nostril of a wearer, for conveying nasal respiratory airflow; and

two cantilevered flow sensor members, each arranged so that at least a portion of the member is located inside a respective said nasal tube, the cantilevered members including piezo-electric material that responds to deflection under the influence of said nasal airflow to generate charge that is indicative of respiratory airflow.

8. Apparatus as claimed in claim 7, wherein each cantilevered member comprises a beam, at the free end of which is provided a paddle.

9. Apparatus as claimed in claim 8, wherein said paddle can be substantially the same shape as the lateral cross-section of the respective nasal tube.

10. Apparatus as claimed in claim 9, wherein the piezo-electric material of each flow sensor comprises a strip that extends longitudinally over at least part of the beam.

11. Apparatus as claimed in claim 10, wherein the piezo-electric material of each flow sensor extends the full length of the beam and over the paddle.

12. Apparatus as claimed in any one of claims 7 to 11, further comprising a body, including a curved plate adapted to be located in the region between the nose and the upper lip of a wearer, and a planar member arranged substantially perpendicular to the curved plate, said nasal airflow sensors being mounted from the planar member.

13. Apparatus as claimed in claim 12, further comprising a cantilevered oral flow sensor member mounted from said body to, in use, be located in front of a wearer's mouth, said oral flow sensor member including piezo-electric material that responds to deflection of said sensor under the influence of oral airflow to generate charge that is indicative of oral respiratory airflow.

14. Apparatus as claimed in claim 12 or claim 13, further comprising straps to releasably secure the body to the wearer's head.

15. Apparatus as claimed in any one of claims 7 to 14, further comprising two planar metallic electrodes sandwiching a strip of said piezo-electric material.

16. Apparatus as claimed in claim 15, wherein said metallic electrodes have an electrical connection to at least a pair of terminals from which an electrical signal indicative of nasal and/or oral respiratory airflow can be obtained.

17. Apparatus as claimed in any one of claims 7 to 16, wherein said piezo-electric material also exhibits pyro-electric characteristics.

18. Apparatus as claimed in claim 17, wherein said piezo-electric material is polyvinylidene fluoride (PVDF).

19. Continuous positive airway pressure (CPAP) treatment apparatus providing different CPAP treatment pressures during inspiration and respiration respectively, the apparatus comprising:

a controllable flow generator for the supply of breathable gas at pressures elevated above atmospheric pressure;

a delivery tube coupled to the flow generator;

a patient mask coupled to the delivery tube to receive said supply of breathable gas;

cantilevered flow sensor means being that can deflect under the influence of patient respiratory airflow and that includes piezo-electric material that responds to said deflection to generate an electrical signal indicative of respiratory airflow; and

control means operable to control said flow generator and, in turn, the pressure of said supplied breathable gas, and to receive said electrical signal and sense transitions between inspiration and respiration therefrom for said different CPAP treatment pressures.

20. A pressure transducer comprising a cantilevered beam that includes over at least a portion of its length a piezo-electric material that develops charge in response to deflection of the beam in response to gas flow.

21. A pressure transducer as claimed in claim 20, wherein said cantilevered beam further includes a paddle at its free end.

22. A pressure transducer as claimed in claim 21, wherein said paddle is disc-shaped.

23. A method for monitoring nasal and/or oral respiration, the method comprising the steps of:

subjecting piezo-electric material to respectively nasal and/or oral airflow to result in a mechanical strain applied to said material thereby inducing an electrical charge; and

collecting said charge by electrodes coupled to said piezo-electric material to form an electrical signal indicative of nasal and/or oral respiration.

24. A method as claimed in claim 23, comprising the further step of calibrating said electrical signal to quantitatively measure nasal respiratory airflow.

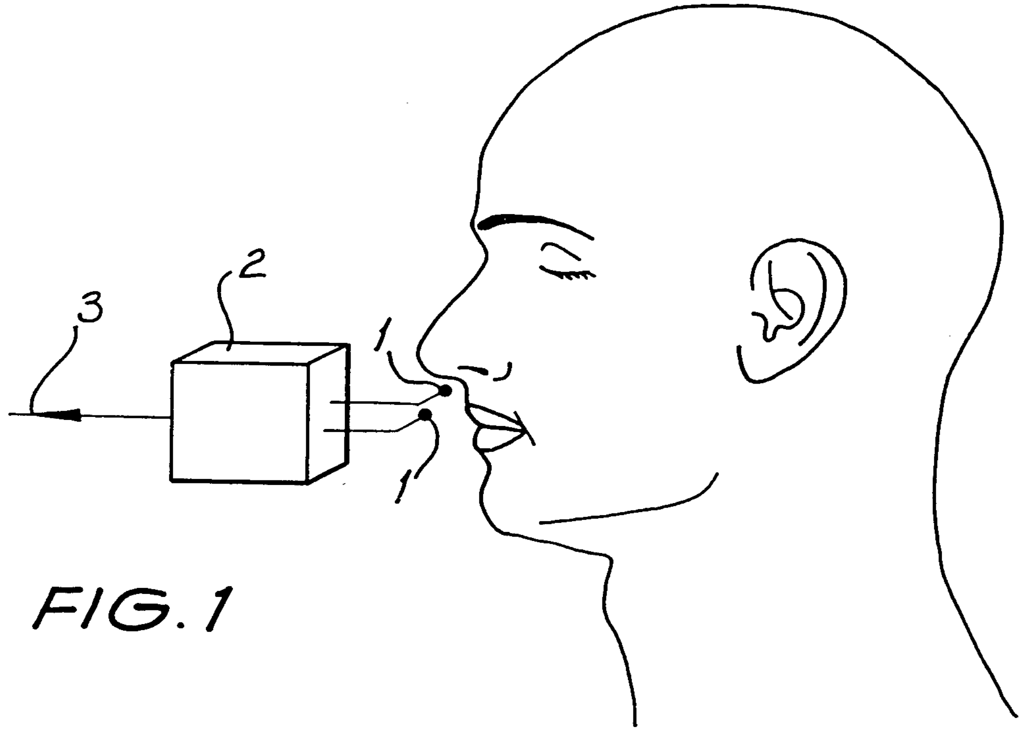

2
3
1
1

FIG. 1

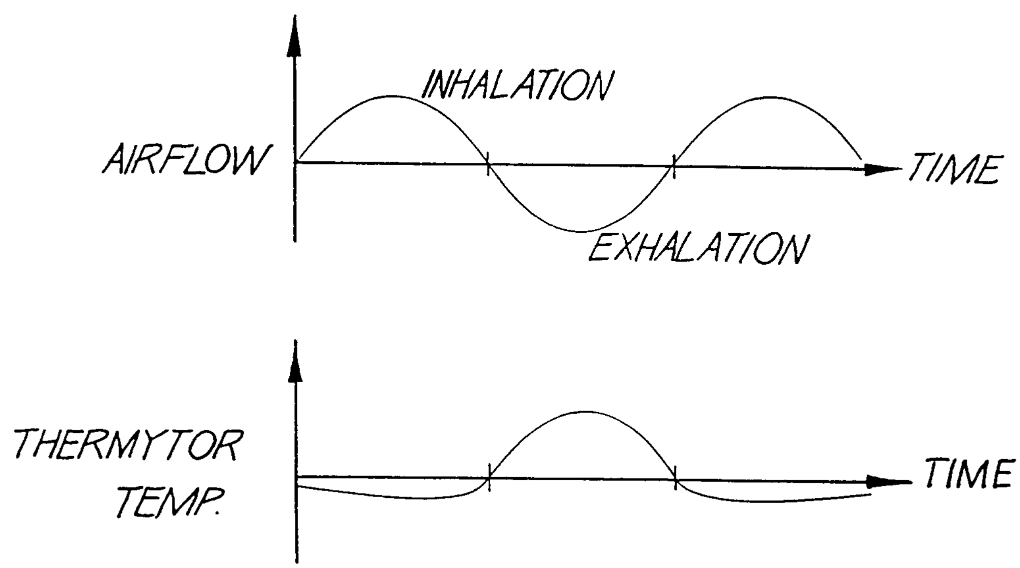

INHALATION
AIRFLOW
TIME
EXHALATION
THERMYTOR
TEMP.
TIME

FIG. 2

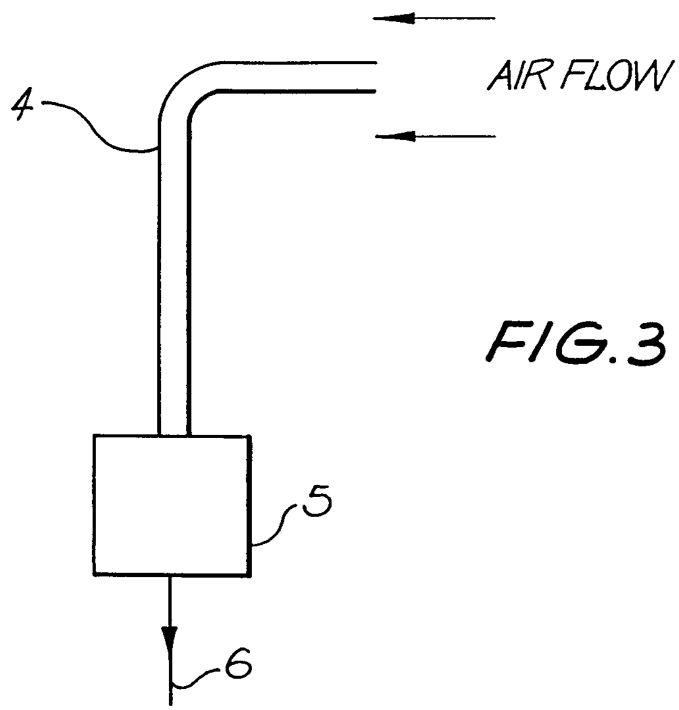


FIG. 3

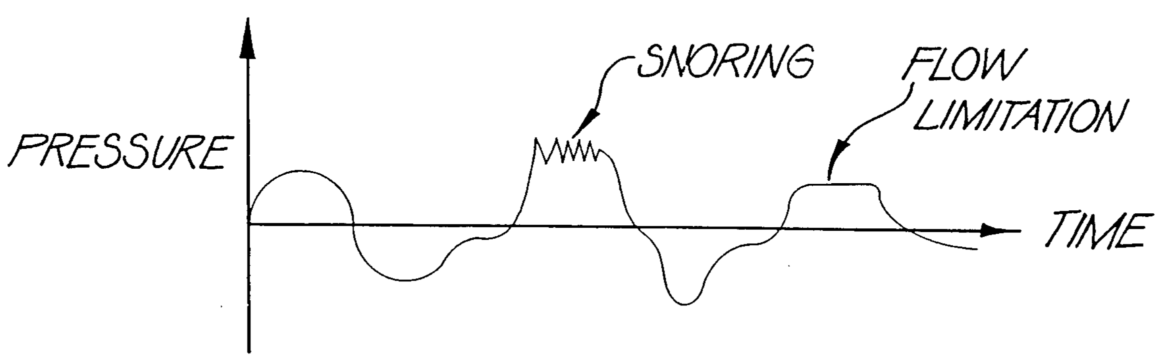


FIG. 4

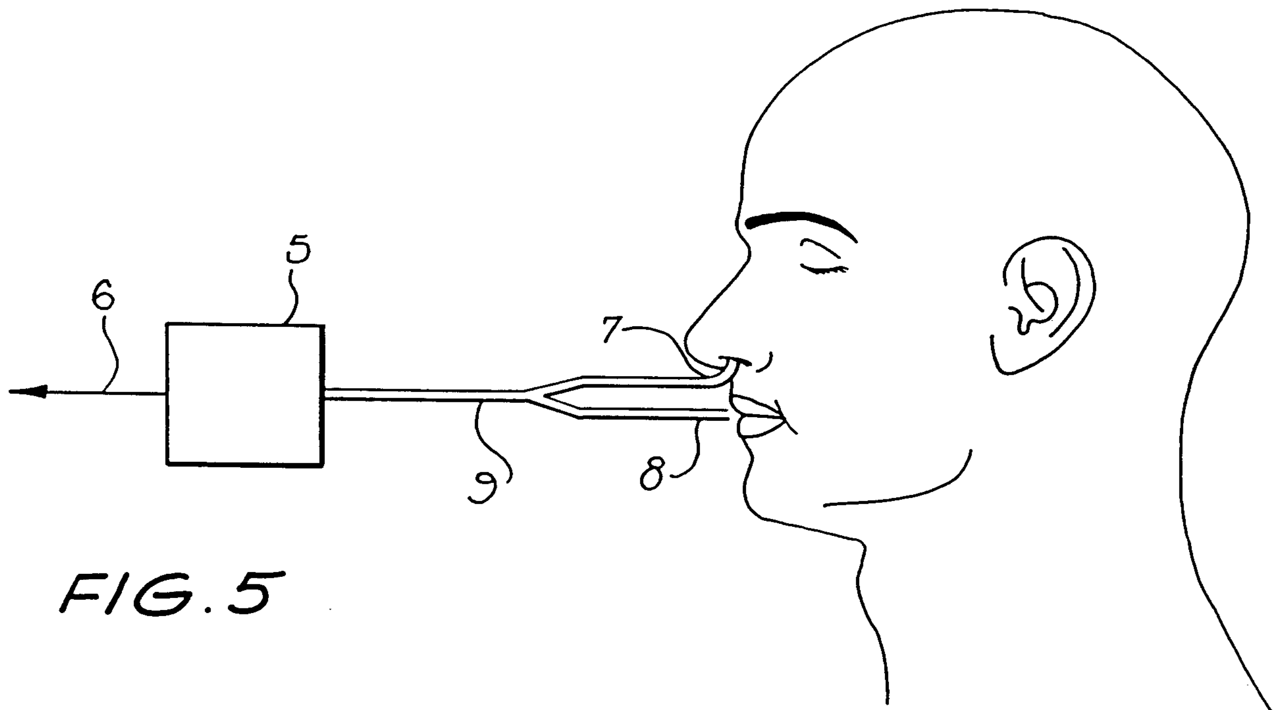


FIG.5

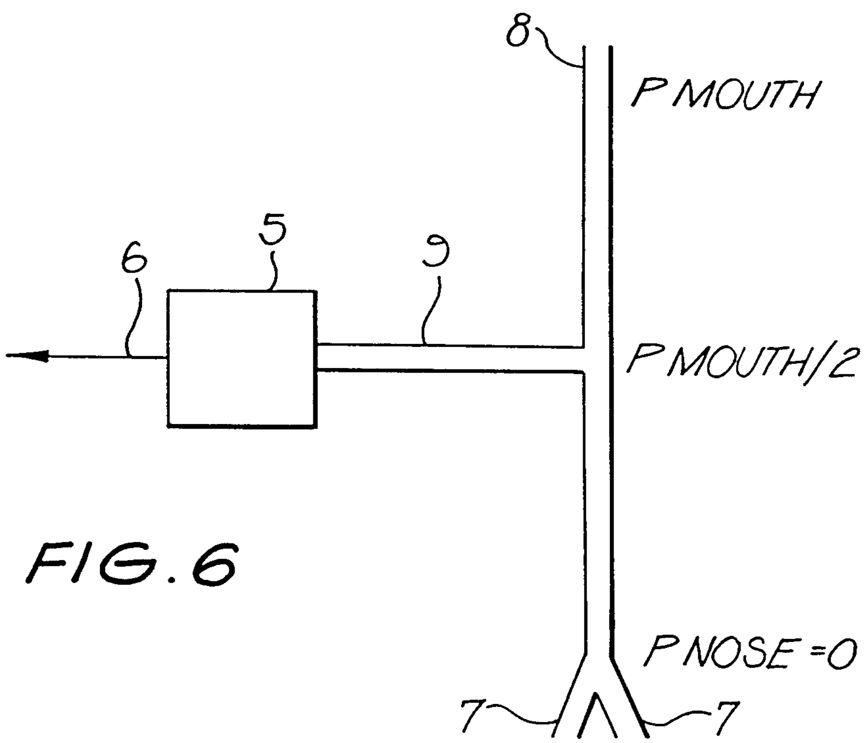


FIG.6

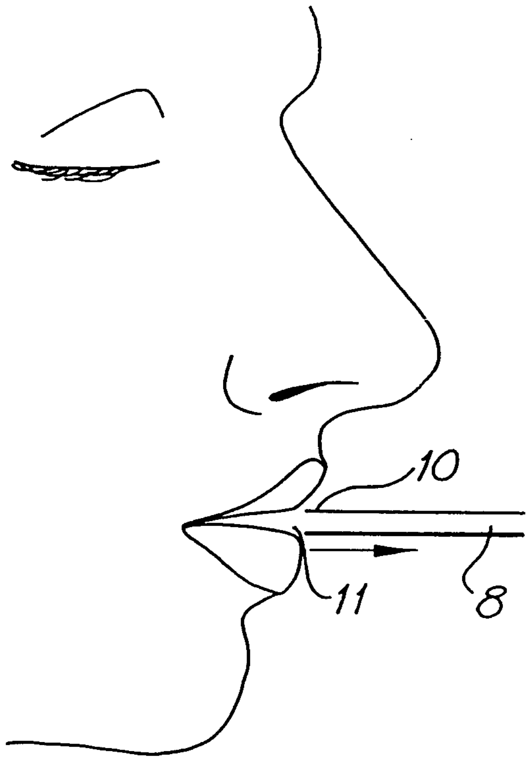


FIG.7a

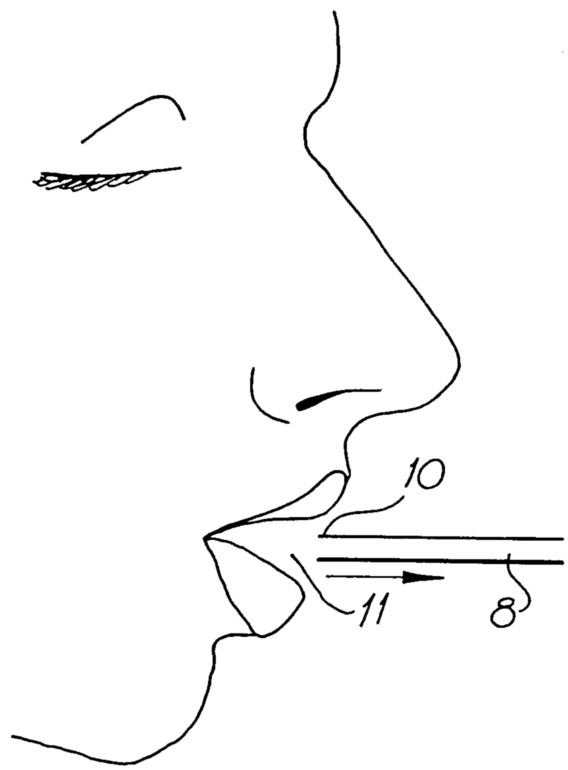


FIG.7b

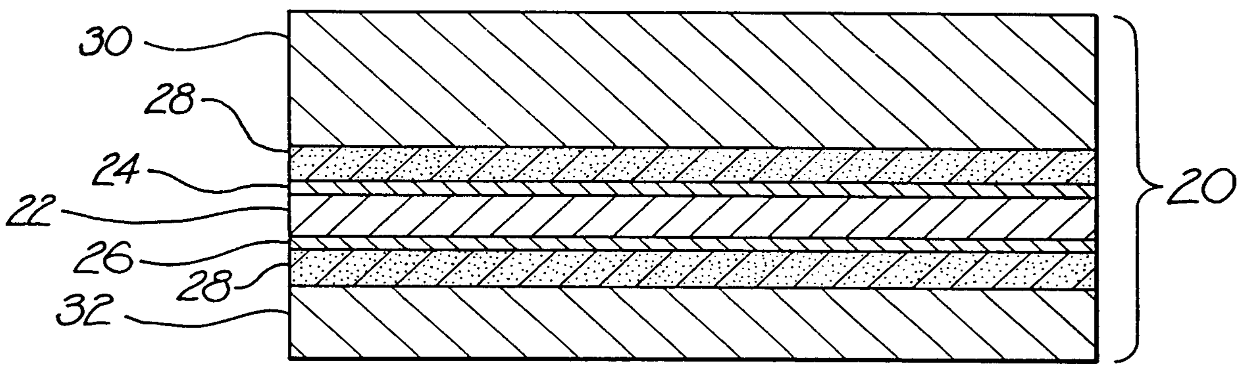


FIG. 8

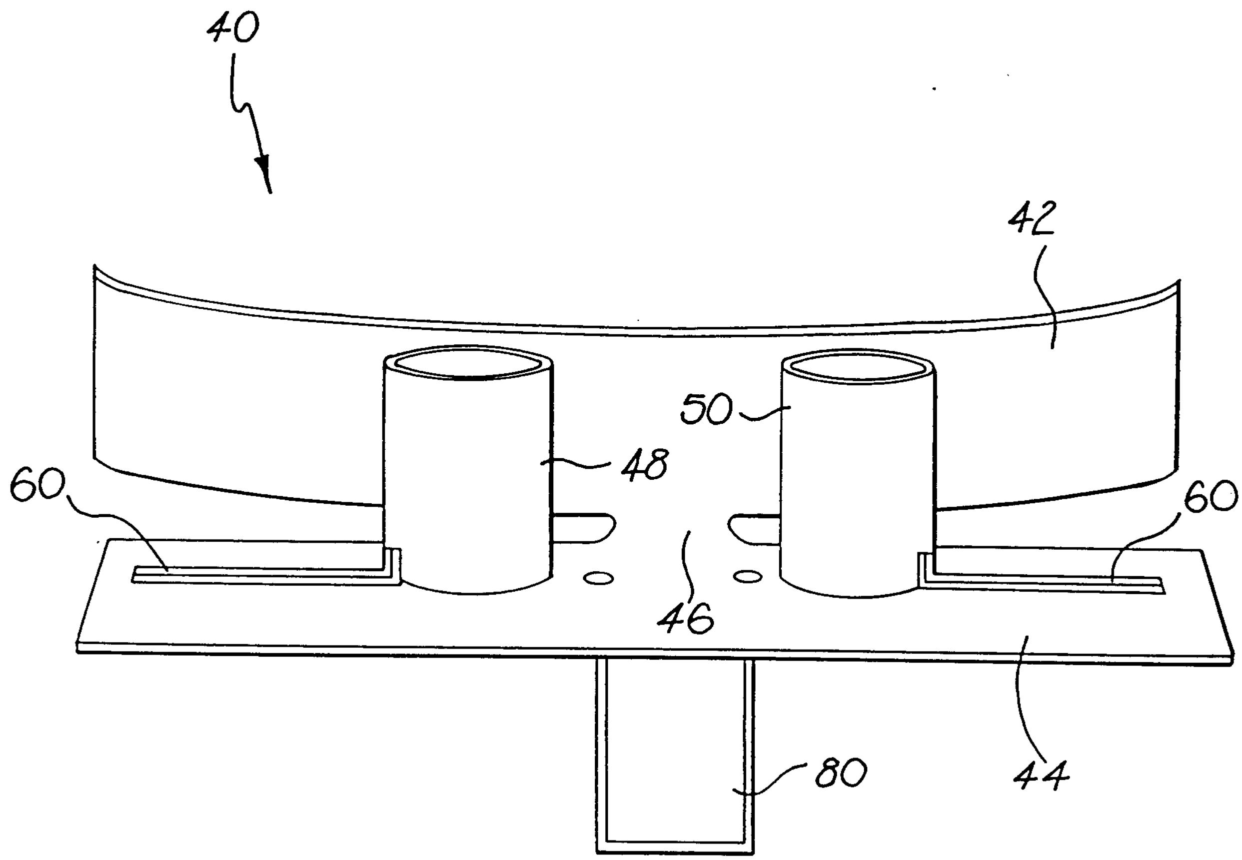


FIG. 9

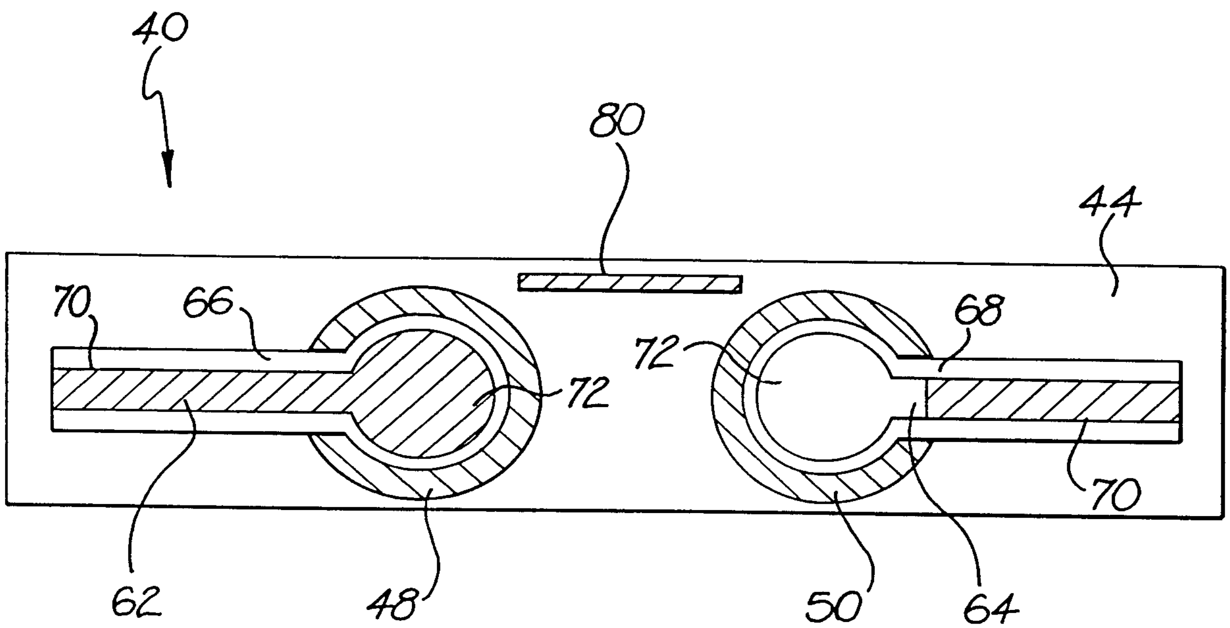


FIG. 10

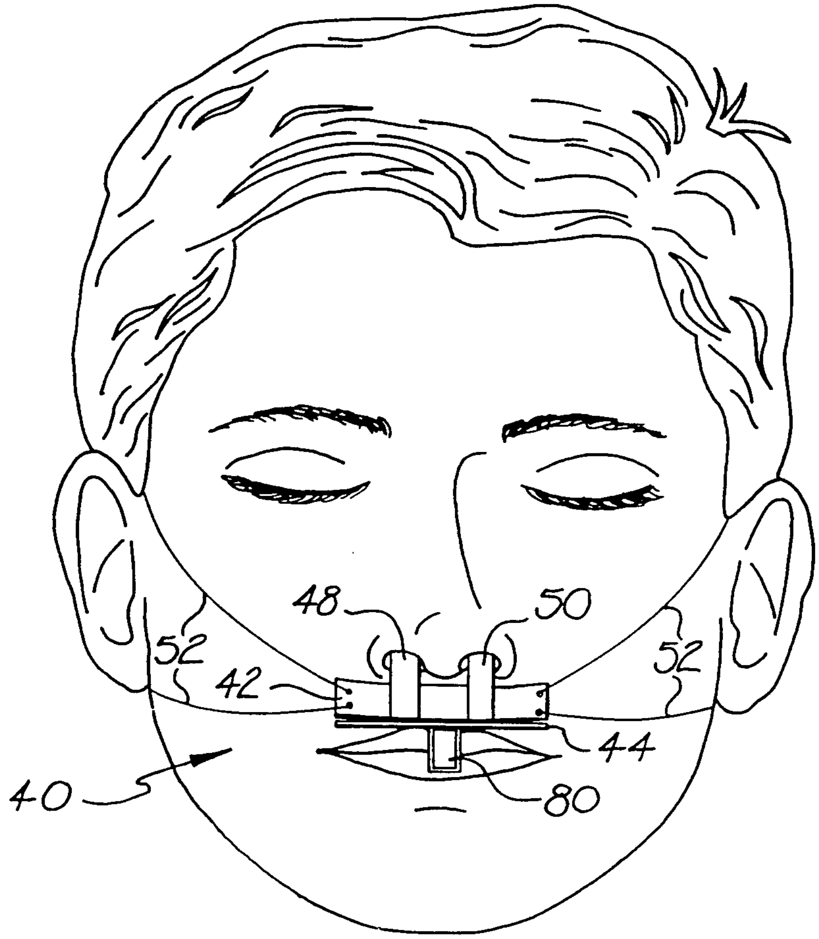


FIG. 11

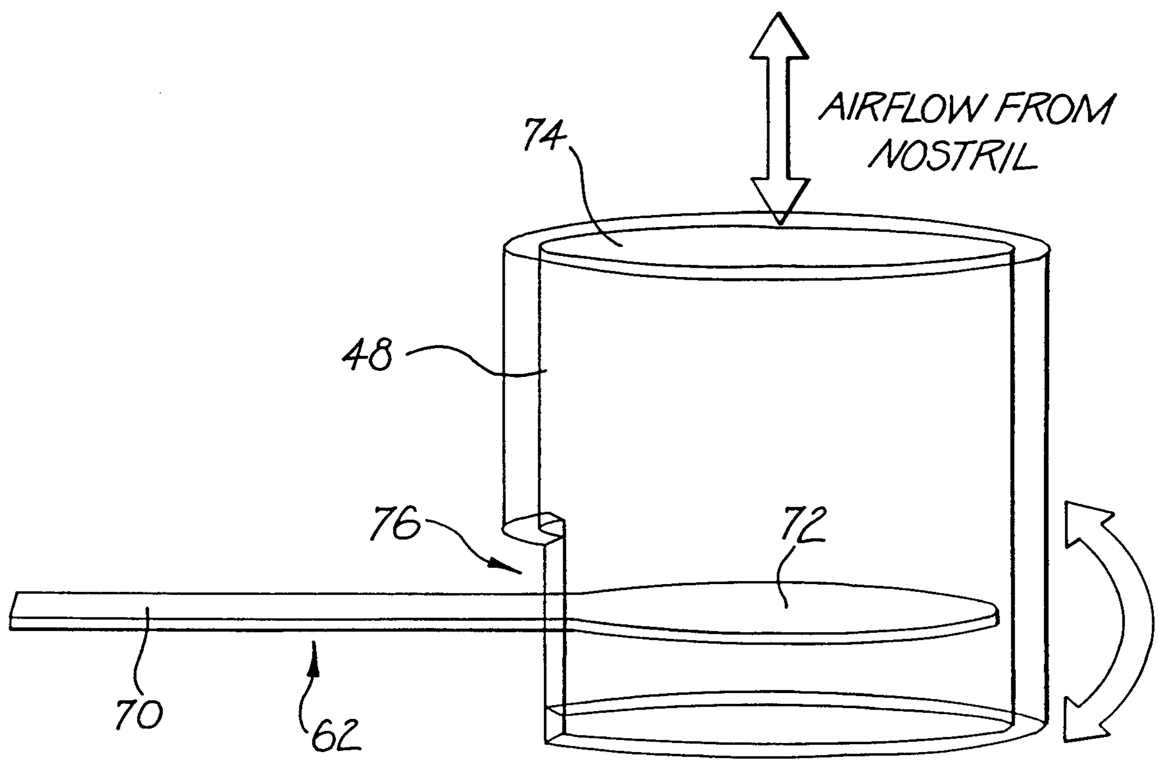
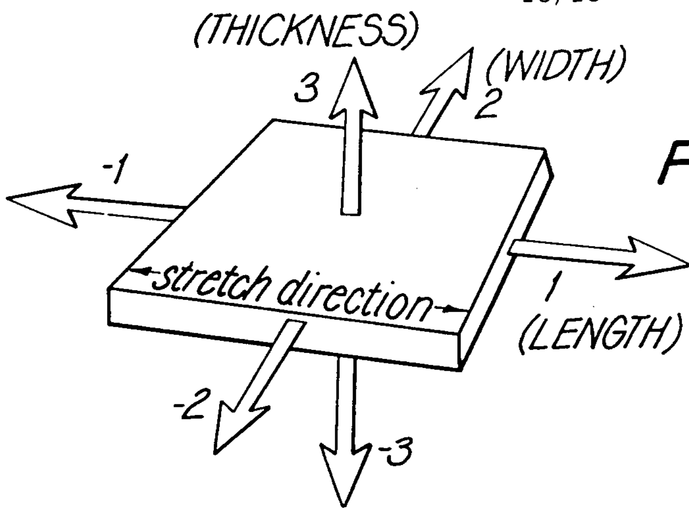
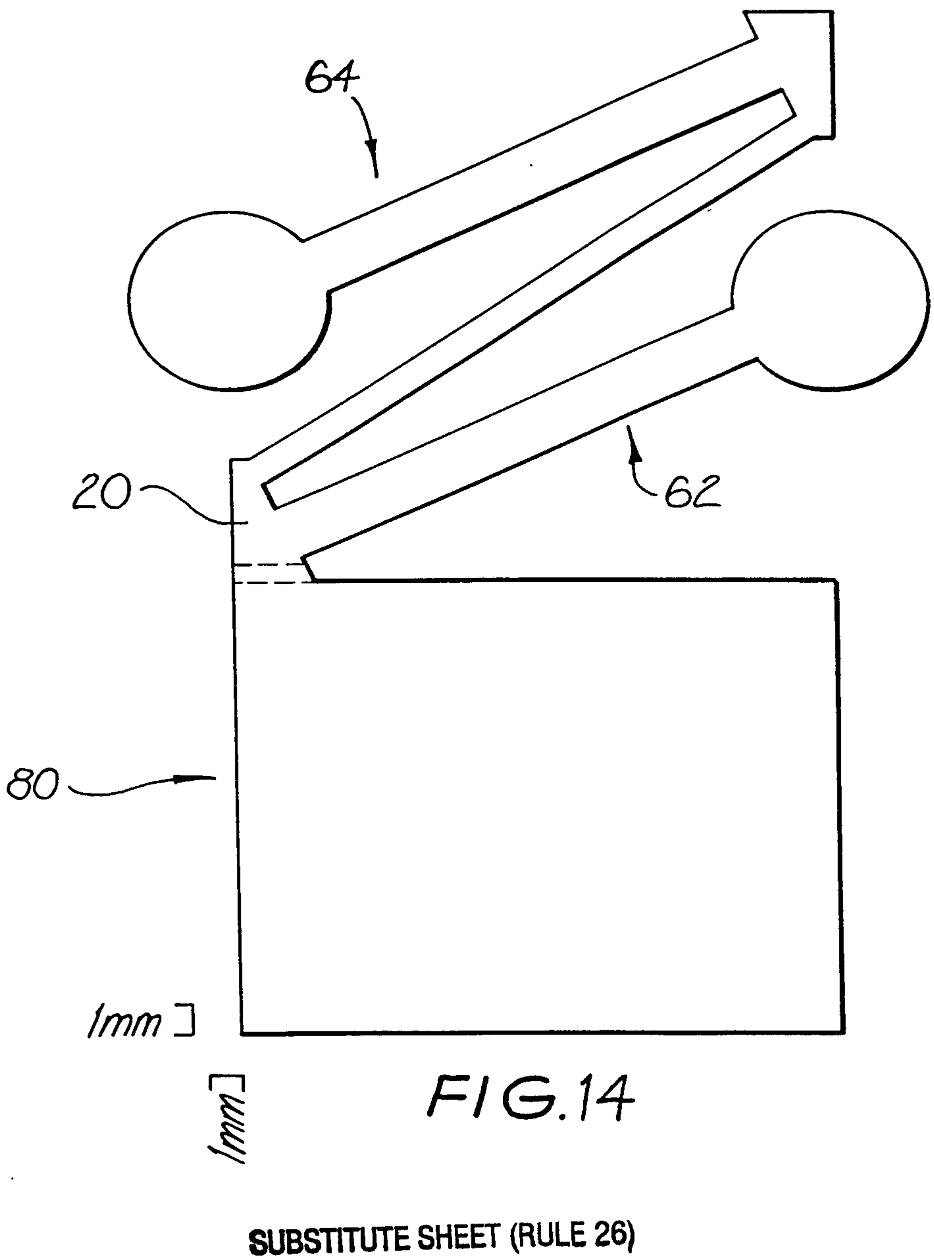


FIG. 12



(THICKNESS)
3
(WIDTH)
2
-1
stretch direction
1
(LENGTH)
-2
-3

FIG. 13



64
20
62
80
1mm
1mm

FIG. 14

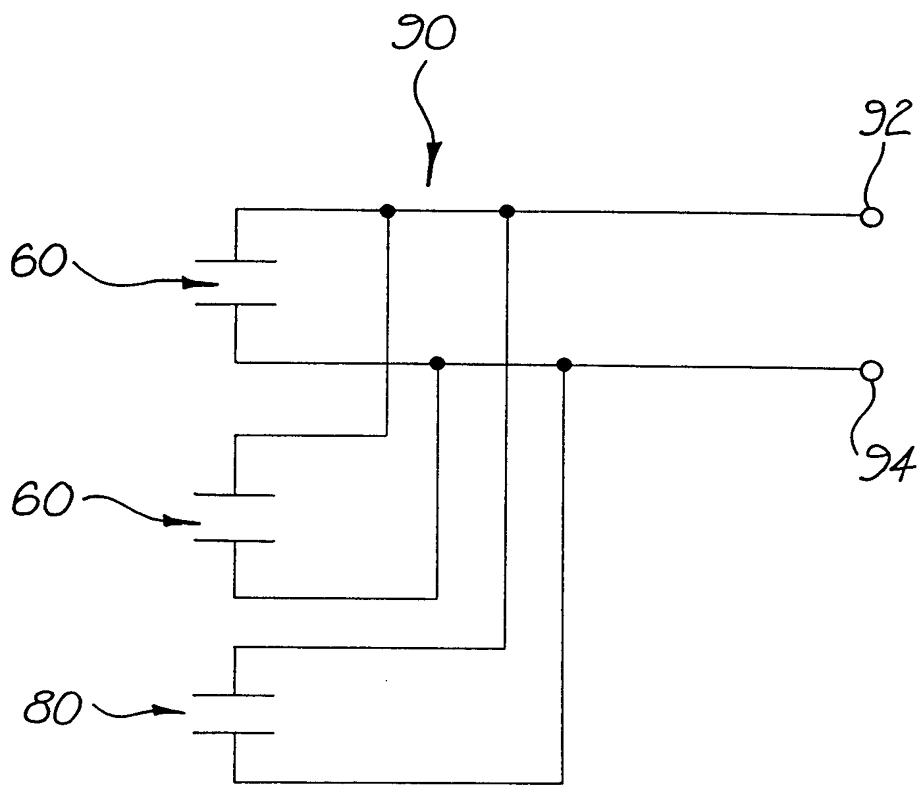


FIG. 15

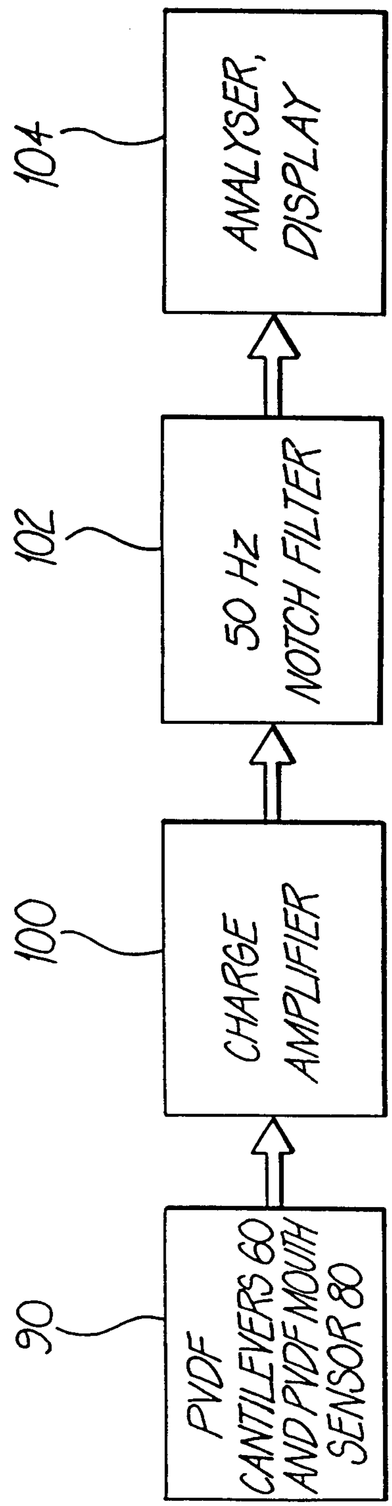

104
ANALYSER, DISPLAY
102
50 Hz NOTCH FILTER
100
CHARGE AMPLIFIER
90
PVDF CANTILEVERS 60 AND PVDF MOUTH SENSOR 80

FIG.16

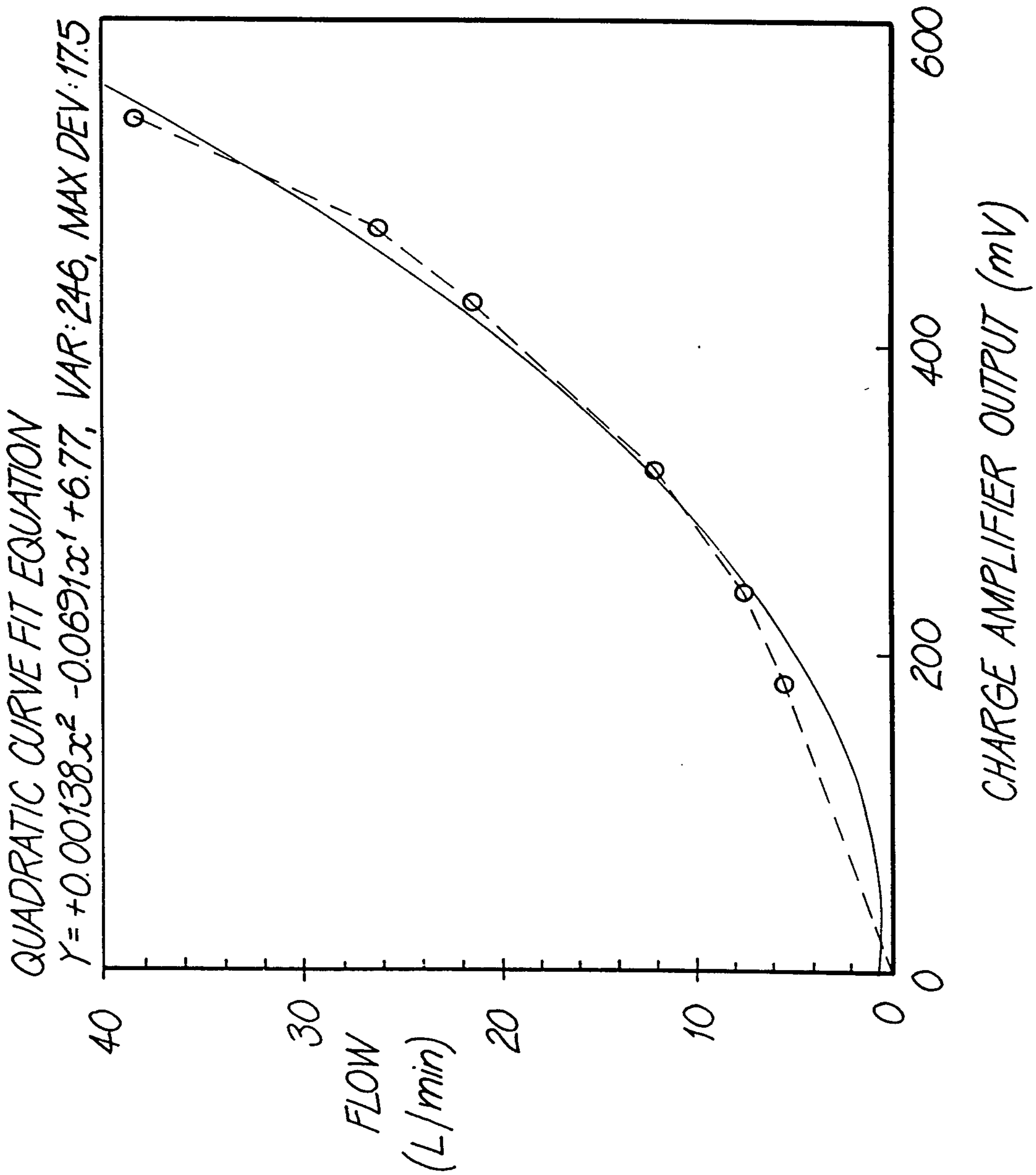

QUADRATIC CURVE FIT EQUATION
Y= +0.00138x² -0.0691x¹ +6.77, VAR:246, MAX DEV:17.5
40
30
20
10
0
FLOW
(L/min)
0
200
400
600
CHARGE AMPLIFIER OUTPUT (mV)

FIG.17

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00500

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl^{6}: A61B 5/087 G01F 1/28 H01L 41/113

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61B 5/08, 5/087,5/09 A61M 16/00 G01F 1/28, 1/64, 1/72 G01L 9/08 H01L 41/04, 41/053, 41/08, 41/113.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU IPC: as above.

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DERWENT: PIEZO()ELECTRIC, CANTILEVER, PIVOT, ROTAT, BEND

JAPIO: as above

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4802485 A (BOWERS et al) 7 February 1989 column 1 lines 43-57, column 4 line 40 to column 5 line 46, figure 4	1-6, 23-24
Y		7 - 18
Y	WO 89/09565 A (B0WE et al) 19 October 1989 pages 2 and 6, figures 1 and 6	1-18, 23-24

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 September 1996	4 October 1996.

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (06) 285 3929	**MATTHEW FORWARD** Telephone No.: (06) 283 2606

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 461281 A1 (ATOCHEM NORTH AMERICA, INC.) 18 December 1991 column 1 line 46 to column 2 line 27, cloumn 5 lines 12 to 36, column 6 lines 12 to 31, column 10 line 32 to column 11 line 51, figures 2 and 6	1-6, 23-24. 7-18
Y	US 4989599 A (CARTER) 5 Feburary 1991 column 1 lines 5 to 33, figure 5	1-18,23-24
X Y	US 5311875 A (STASZ) 17 May 1994 column 2 lines 3 to 48, column 3 lines 2 to 61, figure 1, claim 1	23-24 1-18
Y	WO 94/20018 A (PURITAN-BENNETT CORP) 15 September 1994 see whole document	1-18, 23-24
X Y	US 4312235 A (DAIGLE) 26January 1982 column 3 lines 18 to 39, column 5 lines 38 to 62, figures 2 and 3	20-22 1-19, 23-24
X Y	GB 2221302 A (PA CONSULTING SERVICES LIMITED) 31 January 1990 page 3 to 4, 6 to 7, figures 3(a), 5 to 7	20-22 1-19, 23-24
X Y	Patent Abstracts of Japan, P1373, page 73 JP 04-070516 A (YAZAKI CORP) 5 March 1992 Abstract and figure	20-22 1-19, 23-24
P,X P,Y	WO 95/34917 A (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 21 December 1995 see whole document	20-22 1-19, 23-24
Y	EP 425092 A1 (RESPIRONIC INC) 2 May 1991 column 1 line 46 to column 2 line 27, column 5 lines 2 to 36, column 6 lines 12 to 31, column 10 lines 32 to column 11 line 51, figures 2 and 6	19
Y	WO 92/22244 A (AXE et al) 23 December 1992 page 3 line 12 to page 4 line 26, page 5 line 8 to page 6 line 7, figure 1	19
Y	WO 93/21982 A (NEW YORK UNIVERSITY) 11 November 1993 see whole document	19

Box 1 **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

The independent claims 1, 7, 19, 20 and 23, have as their unifying element a cantilevered or responsive to flows piezo-electric sensor. This device is known in the art, hence multiple inventions are defined 'a posteriori"

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU96/00500

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

WO	89/09565	AU	34467/89	EP	364567	US	5335656
EP	461281						
US	4989599	EP	521874	CA	2072869		
US	5311875						
WO	94/20018	AU	63565/94	EP	687161	US	5443075
US	4312235						
GB	2221302						
JP	04 - 070516						
WO	95/34917	AU	24677/95				
EP	425092	AU	62221/90	AU	38508/93	AU	30678/95
		CA	2024477	JP	3222963	US	5148802
		US	5239995	US	5433193	US	5313937
WO	92/22244	AU	21892/92	CA	2111324	EP	592492
		US	5203343	US	5458137		
WO	93/21982	AU	42405/93	EP	639088	US	5335654
		US	5535739	US	5546933	US	5490502